510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
Gyrus ACMI *Uro - EZDilate Ureteral Balloon Dilation Catheter*

General Information

Contract Manufacturer:	Future Matrix Interventional, Inc. 1605 Enterprise Street Athens, TX 75751 Phone: 903-677-9166
Establishment Registration Number:	1646831
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Neil Kelly Regulatory Affairs Specialist 508-804-2690 Neil.kelly@olympus-osta.com
Date Prepared:	July 12, 2013

OCT 2 1 2013

Device Description

Classification Name:	Dilator, Urethral Dilator, Catheter, Ureteral 21 CFR 876.5470, 876.5520 EZN, KOE Class II Gastroenterology/Urology
Trade Name:	Gyrus ACMI *Uro – EZDilate Ureteral Balloon Dilation Catheter*
Generic/Common Name:	Balloon Dilation Catheter

Predicate Devices

Boston Scientific UroMax Ultra	K130804

Product Description

The Gyrus ACMI Uro – EZDilate Ureteral Balloon Dilation Catheter is a reinforced catheter attached to a distal dilatation balloon. It has a radiopaque tip and two radiopaque markers positioned inside the balloon that define the working length. The balloon catheter can be used to dilate strictures of the urinary tract.

Technological Characteristics

The Gyrus ACMI Uro – EZDilate Ureteral Balloon Dilation Catheter is a reinforced catheter attached to a distal dilatation balloon. Upon inflation, a radial force is delivered over the length of the balloon. A hydrophilic coating applied to the balloon increases ease of insertion, positioning of the balloon within the ureter, and device removal.

The dilation catheter(s) is sold separately, or as part of a kit containing an inflation device. The inflation device is also available for individual sale.

Material

A polycarbonate two-way hub at the proximal end leads into a polyurethane strain relief and into polyamide outer tube. The Polyethylene Terephthalate balloon joins the outer catheter body and sits over a non-patient contacting loaded polyamide inner catheter body. A guidewire is positioned within the patient and the proposed device is then fed over the guidewire and into position.

Intended Uses

The Gyrus ACMI Uro – EZDilate Ureteral Balloon Dilation Catheter is recommended for dilation of the urinary tract.

Compliance to Voluntary Standards

The design of the proposed device complies with the following standards:

ISO 10993-5, 2009
ISO 10993-10, 2010
ANSI/AAMI/ISO 11607-1, 2006
ANSI/AAMI/ISO 11135-1, 2007
ISO 14971, 2007

Summary of Sterilization and Shelf Life Discussion

The Gyrus ACMI Uro – EZDilate Ureteral Balloon Dilation Catheter is delivered in a sterile state and is intended for single patient use only. The sterilization method used is ethylene oxide and has a shelf life of one(1) year.

Summary of Performance Testing

The following performance tests were conducted:

- First Article Inspection
- Balloon Burst Testing
- Balloon Kink Testing
- Durability Testing (cycle testing)
- Compliance Testing
- Balloon Shape Characteristics Testing
- Balloon Insertion Force Testing
- Balloon Cystoscope Compatibility Testing
- Balloon Deflation Testing

Substantial Equivalence

The proposed Gyrus ACMI Uro – EZDilate Ureteral Balloon Dilation Catheter has the same intended use, design, and scientific technology as the Predicate Boston Scientific UroMax Ultra Balloon Dilation Catheter (K130804). Both devices are of similar design and there were no new issues of safety or effectiveness with the proposed device.

Conclusion:

In summary, the Gyrus ACMI Uro – EZDilate Ureteral Balloon Dilation Catheter is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 21, 2013

Olympus Surgical Technologies America
Gyrus ACMI
% Neil Kelly
Regulatory Affairs Specialist
136 Turnpike Road
Southborough, MA 01772

Re: K132181
Trade/Device Name: Gyrus ACMI Uro – EZDilate Ureteral Balloon Dilation Catheter
Regulation Number: 21 CFR§ 876.5470
Regulation Name: Ureteral dilator
Regulatory Class: II
Product Code: EZN, KOE
Dated: September 25, 2013
Received: September 26, 2013

Dear Neil Kelly,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: Gyrus ACMI Uro – EZDilate Ureteral Balloon Dilation Catheter

510(k) Number: TBD K132181

Indications for use:
The Gyrus ACMI Uro – EZDilate Ureteral Balloon Dilation Catheter is recommended for dilation of the urinary tract.

Prescription Use: __ X __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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